

Appl. No. : 10/036,041
Filed : December 26, 2001

REMARKS

Claims 22-26, 36 and 38-45 are pending as set forth above. Claim 35 has been cancelled without prejudice toward future prosecution. New Claims 42-51 have been added as set forth above. The subject matter of Claims 42-45 was previously presented generally as Claims 27-29 and 32, respectively, which were previously cancelled without prejudice toward future prosecution in the amendment filed on November 20, 2003. Support for new Claims 46-51 is found in the application as filed, for example, specifically in Figure 2 and at page 64, line 30 to page 67, line 16. Claim 36 has been amended as set forth above with additions shown by underlined text and deletions shown by ~~striktthrough-text~~. No other claim amendments have been made and no new matter has been added.

Correction of Inventorship under 37 C.F.R. § 1.48(b) (Deletion of Inventors)

Due to the previous amendments to the claims, amendment of the inventorship is requested as set forth in the "Request to Correct Inventorship Under Rule § 1.48(b)," on page 8 of this paper.

Discussion of Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 35 and 36 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Particularly, the Examiner asserts that Claim 35 is incomplete for omitting essential elements because the "stringent conditions" are not recited in the claim nor are process steps that would effect the removal of non-specific hybridization complexes.

Claim 35 has been cancelled. Claim 36 recites specific stringent conditions. Furthermore, Claim 36 has been amended, as set forth above, to include all of the limitations of cancelled Claim 35. Therefore, amended Claim 36 is complete, and Applicants respectfully request reconsideration and withdrawal of the instant rejection under the second paragraph of § 112.

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Discussion of Rejections under 35 U.S.C. § 112, First Paragraph

Enablement

Claims 35 and 36 remain rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. According to the Office Action, the specification does not reasonably provide enablement for the isolated nucleic acid hybridization variants set forth in the claims. According to the Office Action, the invention is not commensurate in scope with Claim 35.

As mentioned above, Claim 35 has been cancelled. Claim 36 has been amended to recite isolated nucleic acids that hybridize under specified stringent conditions. The specific conditions are recited in the claim, namely:

50% formamide;
5 x SSC (0.75 M NaCl, 0.075 M sodium citrate);
50 mM sodium phosphate (pH 6.8);
0.1% sodium pyrophosphate;
5 x Denhardt's solution;
sonicated salmon sperm DNA (50 micrograms/ml)
0.1% SDS, and 10% dextran sulfate at 42°C;
washes at 42°C in 0.2 x SSC (sodium chloride/sodium citrate) and 50%
formamide at 55°C; and
a high-stringency wash consisting of 0.1 x SSC containing EDTA at 55°C.

Therefore, amended Claim 36 is enabled because one of ordinary skill in the art can easily make and use the claimed hybridization variants without undue experimentation by following the specified conditions.

Thus, enablement is commensurate in scope with the amended claims. For these reasons, reconsideration and withdrawal of the enablement rejection in view of the amendments to the claims is respectfully requested.

Written Description

Claim 35 and 36 are rejected under 35 U.S.C. § 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to reasonably convey

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to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Again, Claim 35 has been cancelled. Claim 36 has been amended to recite the specific hybridization conditions under which the isolated nucleic acid variants hybridize. The recited conditions are disclosed in the specification as filed. Therefore, one of ordinary skill in the relevant art would recognize that Applicants possessed the claimed hybridization variants at the time the application was filed. Reconsideration and withdrawal of the instant written description rejection under § 112, first paragraph, is respectfully requested.

Discussion of Rejections under 35 U.S.C. § 102(e)

Claims 22-26, 35-36 and 38-41 remain rejected under 35 U.S.C. § 102(e) as being anticipated by Piddington et al., U.S. Patent No. 6,521,233 (referred to hereafter as “Piddington”). Attached herewith is the Declaration of Luc Desnoyers and William I. Wood under 37 C.F.R. § 1.131 (referred to hereafter as “the Declaration of Desnoyers and Wood”). The Declaration of Desnoyers and Wood establishes that the presently claimed subject matter was conceived prior to the earliest effective publication date of Piddington, April 20, 1999, and diligently reduced to practice on a date after the Piddington effective date.

As set forth in 37 C.F.R. § 1.131, a patent applicant “may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based.” *See also*, M.P.E.P. § 715. “The affidavit or declaration must state FACTS and produce such documentary evidence and exhibits in support thereof as are available to show conception and completion of the invention in this country ... at least conception being at a date prior to the effective date of the reference.” *See* M.P.E.P. § 715.07 (emphasis in original). The showing of facts must be sufficient to show “conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to a subsequent (actual) reduction to practice.” *See id.*

Piddington is based upon a nonprovisional application that was filed on April 19, 2000, but which claimed priority to U.S. Provisional Application No. 60/130,199, which was filed on April 20, 1999. Therefore, the earliest effective publication date of Piddington is April 20, 1999. Piddington is cited as a 102(e) reference because it allegedly discloses nucleotides 9-1704 of SEQ ID NO:1 (1712 nucleotides) from the instant application. However, as set forth below,

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Applicants were in possession of SEQ ID NO:1 prior to the effective publication date of Piddington.

The Declaration and attached Exhibit A demonstrate that the claimed subject matter, particularly a nucleic acid having the sequence of SEQ ID NO:1, was conceived by Applicants prior to April 20, 1999. Furthermore, as evidenced by the Declaration and Exhibits B-C, Applicants exhibited diligence in reducing the subject matter of the claims to practice from at least just prior to the Piddington effective date, by performing various assays to confirm the function of the polypeptide. Finally, as demonstrated by Exhibits D and E, the subject matter of the claims was reduced to practice on November 10, 1999. The Declaration and Exhibits are discussed in further detail below.

Conception of SEQ ID NO:1

Prior to April 20, 1999, the idea of investigating several newly discovered nucleic acid sequences for their relevance was conceived. Exhibit A is a sequence map showing a nucleic acid having the full sequence of SEQ ID NO:1, as well an amino acid encoded by the sequence. As set forth in the attached Exhibit A, Applicants possessed the entire sequence of SEQ ID NO:1 at a date prior to April 20, 1999.

Diligence in Reducing the Claimed Subject Matter to Practice

After obtaining the nucleic acid having the sequence of SEQ ID NO:1, Applicants worked diligently to reduce the claimed subject matter to practice. The cDNA was deposited with the American Type Culture Collection (ATCC) on January 12, 1999 and assigned ATCC no. 203581. As evidenced by Exhibits B-D, Applicants worked systematically to express and purify the encoded polypeptide and to run it through a large number of assays. As evidenced by Exhibit B, the polypeptide was expressed in *E. coli*, *Baculovirus*, and in mammalian cells. Also, various constructs with tags, such as poly-His or IgG tags, were made starting from the time of first cloning. The construction of these was followed by expression and purification of the encoded protein during the time period of prior to April 20, 1999 through March 13, 2003. Exhibit C shows one such purification that was completed on July 13, 1999. The purified proteins were distributed to various scientists for multiple cell-based assays and/or quality confirmation tests from August 20, 1999 through January 22, 2001. Many of the assays are listed on Exhibits D

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and E. Thus, Applicants showed diligence from prior to April 20, 1999 up until an actual reduction practice, which occurred on November 10, 1999 as explained more fully below.

Reduction to Practice

Exhibit D demonstrates, at least in part, the large variety of assays performed as part of the large screening system for the encoded polypeptide. Exhibit E shows the results of several chondrocyte redifferentiation assays demonstrating a function for the encoded polypeptide. For one of the assays, samples of the encoded polypeptide were distributed to the inventor on October 22, 1999, and the assay was completed on November 10, 1999 with results demonstrating the activity of the polypeptide. Therefore, the claimed nucleic acids were reduced to practice at least by November 10, 1999.

As set forth above, and as evidence by the attached Declaration under § 1.131 with the accompanying exhibits, Applicants conceived the claimed subject matter prior to April 20, 1999, then worked diligently from before April 1999, until November 10, 1999 to reduce the claimed nucleic acids to practice.

Thus, Piddington does not anticipate Claims 22-26, 35-36 and 38-51 because Applicants conceived the claimed subject matter prior to the effective publication date of Piddington, and thereafter diligently reduced it to practice. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims under 35 U.S.C. § 102(e) over Piddington.

Conclusion

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, the arguments in support of the patentability of the pending claim set are presented above. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

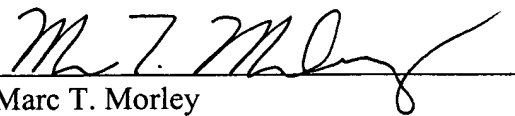
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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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